

Presentation at Part 15 hearing on Homeopathic Product Regulation

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My Credentials

- Currently the President of the Center for Education and Development of Homeopathy (CEDH) in the U.S. (see below)
- A member of the Homeopathic Pharmacopeia of the United States (HPUS)
- A founding member of the International Medical Homeopathic Organization (OMHI) and an honorary member of the South African Medical Homeopathic Association
- I have a Doctorate in Medicine and two homeopathic specialty degrees from both of France's premier accrediting homeopathic educational institutions.
- I am the co-author of ten books on homeopathy and have treated patients with homeopathic medicines for more than 30 years.

About the CEDH

- CEDH offers licensed physicians training on clinical homeopathy. Its purpose is to give physicians the most reliable knowledge of homeopathy in a clear, pragmatic and clinical approach. It is the largest clinical homeopathic school in the world and stands on its 43-year old reputation. (www.cedhusa.org)
- Nearly 3,000 physicians are trained per year in more than 20 countries, including the U.S.
- In the U.S., the CEDH has contributed to public health by educating more than 1,000 medical professionals.
- Registration is open to licensed MDs, DOs, PAs, NPs and midwives.
- Courses are taught to licensed physicians with practical experience and clinical knowledge.

Q#1: What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

HCP attitudes toward homeopathy is extremely positive. Attendance has grown for a couple of reasons:

- HCPs want the knowledge to answer patient questions as more people proactively ask their doctors about homeopathic medicines.
- More HCPs are seeking different toolsets to better help their patients. They are attracted and curious about homeopathy as a low-risk option.
- More HCPs want to differentiate their practice by offering a range of therapeutic methods.

- HCPs choose to invest \$1,600 in registration and much time traveling and attending the 8-weekend course offered in 7 U.S. cities. My student doctors' experiences with homeopathic medicine after graduation serve as examples of HCP attitudes toward integrating these products into their practice:

Albert Levy, MD, FAAFP, New York, N.Y.:

- “I am a family physician and I incorporate homeopathy in my practice when appropriate. My patients love it. They appreciate the fact that there are no side effects, no contraindications and, most importantly, they appreciate that their doctor is open to other methods of therapy.”

Rachel Johns, MSN, CNM & Nancy Loewen, MSN, CNM, Fairhaven Obstetrics & Gynecology, Inc., Goshen Birth Center, Goshen, Ind.:

- “We have patients that ask us for “something else” that will help them during pregnancy, postpartum or with a health problem on a daily basis. We now have a safe, trusted therapeutic alternative to offer to the women we care for. Many have come back to ask us about treatment for family members or have referred other women to us.”

Q#2: What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of homeopathic drug products (HDPs)?

As an institution with the primary goal of contributing to the safe and responsible practice of homeopathy, the CEDH considers itself a source of information. The ultimate goal of our community is to provide the best homeopathic medicines and not to harm our patients.

I have practiced and taught in three continents and I take care to respect the Homeopathic Pharmacopeia of each country. I teach my HCP students to do the following:

- Use medicines that state “HPUS” after active ingredients on the packaging. To me, this ensures the quality of the product, as it is prepared under the HPUS guidelines.
- Refer to the HPUS which indicates which dilutions can be recommended for OTC conditions, Rx conditions, external use, etc.

The same applies to brand-named homeopathic complexes, meaning products that contain at least one monographed HPUS substances *and* has an OTC indication.

Q#8: Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?

If not, what information, including, for example, information in labeling, would allow consumers and health care providers to be better informed about products labeled as homeopathic?

My doctors expect reliable (quality-manufactured) medicines with industry-standard labels bearing clear information, and for these products to be well-stocked in common retail outlets so their patients can conveniently treat their condition. Again, the answer here is very simple. HCPs and consumers alike should check on product labels that HPUS is indicated for the homeopathic active ingredients.

Having HPUS on the label is ONE of the indicators of quality.

Conclusion

The regulation of homeopathic drug products through the 25-year old Compliance Policy Guide (CPG 400 400) has worked well. I believe the vast majority of the products accessible to my doctors and their patients are manufactured and labeled in compliance with the HPUS and the CPG. This ensures high-quality medicines that are easy to identify for health care needs.

The rules and regulations for OTC and Rx homeopathic medicines have been established by the FDA and the HPUS. Since the Homeopathic Pharmacopeia of the United States body does not have regulatory oversight on claims by branded products, my recommendation to the FDA is to enforce the current regulation for products that are manufactured outside of HPUS guidelines.

The many homeopathic products offered by manufacturers and retailers and recommended by physicians extends and provides value like a strong and healthy tree. It would be unproductive to cut the whole tree when only a few troublesome branches need to be pruned.